

**Evaluation of the Implementation of
Maine's Prescription Drug Monitoring Program**

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I. Overview

Maine is one of twenty-two states to implement a Prescription Drug Monitoring Program (PMP), with funding from Harold Rogers Prescription Drug Monitoring Program (U.S. Department of Justice, Bureau of Justice Assistance). Under Maine's PMP, all transactions from pharmacies dispensing prescriptions to Maine residents for Schedules II, III, and IV drugs are submitted electronically to a database, maintained by the Maine Office of Substance Abuse. This database is analyzed to see if anyone has met a threshold for raising a "red flag" that they might have been receiving dangerous levels of prescription drugs. Reports on those who meet the threshold are then generated from the analysis and sent to the clinicians who show up as prescribers of the prescriptions. This information allows clinicians and pharmacies to better administer prescription drugs to limit and curb the dangerous and deadly effects of abuse and overdose. State Legislation creating the program was passed in 2003 and regulations put in place on June 22, 2004.ⁱ Data collection began on July 30, 2004.

The Muskie School, University of Southern Maine, conducted a process evaluation of the implementation of Maine's Prescription Monitoring Program (Maine PMP) in late Summer and Fall 2005. The purpose of the evaluation was to assess how the implementation of the Maine PMP has proceeded, from the perspective of the major stakeholders participating in the development of the PMP and the experience of participating prescribersⁱⁱ and dispensers (pharmacies). Information from this evaluation will be reported to OSA and shared with major stakeholders and participants (prescribers and dispensers) to help guide refinements and improvements in the PMP. The implementation evaluation will also help guide development of the outcome evaluation of the PMP.

The implementation evaluation has three components:

- Key stakeholder interviews with OSA staff, members of the PMP Advisory Committee, and the Data contractor (GHS Data management).
- Survey of dispensers who submit data to the program.
- Survey of prescribers who have registered in the PMP system.

II. Context and Environment

An alarming increase in the abuse of prescription drugs in Maine prompted state policymakers to develop Maine's Prescription Monitoring Program (PMP). Treatment admissions for prescription drug abuse had increased from 83 in 1995 to 1148 in 2003. The number of overdose deaths increased steadily – as did the proportion of these deaths caused by prescription drug abuse. In 2001 there were 90 drug deaths in the state; 70 (78 percent) were caused by a pharmaceutical. One year later, in 2002, the number of overdose deaths had nearly doubled to 166; 148 of these deaths (89 percent) were caused by a pharmaceutical. Arrests for prescription drug diversion increased steadily, accounting for 16 percent of arrests made by Maine Drug Enforcement Agency in 2003. In 2002 more than twenty percent of Maine high school seniors reported that they have used prescription drugs to get high.

Prescription Drug Monitoring Programs in other states, funded by the U.S. Department of Justice, Bureau of Justice Assistance, offered an opportunity and a model to address Maine's growing prescription drug abuse problem. The first Bill to create a Prescription Monitoring Program was introduced in the Maine Legislature in 2001. While there was growing recognition that Maine had a prescription drug problem that needed to be addressed, there was concern that the program should not be used as a tool for law enforcement – as it is in a number of other states. A related concern was that the data collected and used needed to be confidential and secure and be in compliance with emerging HIPAA regulations.

A consensus emerged that a prescription monitoring program should be used as a public health and clinical intervention tool to reduce the illicit use of prescription drugs. Under the leadership of Maine's Office of Substance Abuse and with the participation and support of Maine's medical community, pharmacies, attorney general's office, department of licensure and regulation, and other stakeholders a working consensus was formed for how Maine's Prescription Monitoring Program should work to support this goal. This group evolved into The PMP Advisory Committee. The passage of the Bill in 2003 (on the third try before the Maine Legislature) creating the Prescription Monitoring Program, gave the Office of Substance Abuse the authority to develop the program, but did not authorize a state expenditure. To be implemented, the program would need to secure external funding, which it did in October 2003.

While there was (and remains) substantial support for the PMP when it was created, there are a number of issues that needed to be addressed as the program was developed and implemented and also will require attention as the PMP matures and grows. These issues include:

- Availability of external and continued funding to support the program
- Maintaining patient confidentiality (in terms of HIPPA compliance and using the data for prevention and treatment and not for law enforcement)
- Avoiding a "chilling effect" (where the existence of the PMP may deter persons who need prescription medications from receiving them)
- Data accuracy (ensuring that the data collected and reported is accurate) and usefulness
- Provider consultation (permitting and promoting health care providers to contact each other in the case of suspected problems with patients)

Many data confidentiality issues were addressed in the enabling legislation creating the PMP. In administering the PMP, OSA is designated as a "health oversight agency" under HIPAA. Because the disclosure of information by pharmacies to the PMP is mandated, patient consent is not required. Under the enabling legislation it is a felony to access or disclose PMP information improperly. OSA is only permitted to give PMP reports to law enforcement if they have a court order for such information that pertains to a specific case before the court.

III. Stakeholder Interviews

Interviews were conducted with OSA staff, members of the PMP Advisory Committee, and the Data contractor. While questions varied somewhat for each stakeholder group, stakeholders were asked about their participation in the PMP program, what the major goals of the PMP were, whether the program would be likely to meet these goals in the long-run, how the program was working so far (including the generation and use of data reports), whether they had any issues or concerns, and how program outcomes should be evaluated. Respondents were also asked what two things they would recommend to OSA. Findings from these interviews are synthesized (to preserve respondent confidentiality) below.

Goals and expectations for program: Stakeholders uniformly and enthusiastically reported that the major goal of the Maine PMP was to reduce the illicit use of prescription drugs in Maine by giving prescribers a tool for patient care and for giving both prescribers and dispensers information for identifying patients who might be abusing prescription drugs. Nearly all stakeholders were clear to draw the distinction between these goals and the law enforcement goals found in many other states. A number of stakeholders noted that early and timely clinical intervention was important, before a patient's prescription abuse became more severe or had greater consequences. Several stakeholders indicated that there was also a more global and long-term public health goal for the program, in which the PMP database could be used to show the extent and distribution of prescription drug abuse geographically and by age group across Maine.

Challenges and issues in developing the program: The major issue and concern in developing the program was patient confidentiality. At a political and policy level, this issue was resolved relatively early on. As a technical matter, confidentiality is an ongoing issue that needs to be addressed. As described below, the PMP has very successfully established and maintained confidentiality. However there is an ongoing need to balance access to and speed of data retrieval with the accuracy and confidentiality of the data.

News about how other states used their PMP for law enforcement contributed to some ambivalence and doubts about the program Maine was developing. These doubts were assuaged over time as Maine developed a program clearly focused on prevention and treatment and built in confidentiality safeguards.

Role and function of the advisory committee:

PMP Advisory Committee stakeholders were uniformly effusive in their praise of how the PMP Advisory Committee functioned and was used. The Advisory Committee provided an important and productive forum for identifying and resolving potential problems. Stakeholders reported that the OSA Director listened and responded to stakeholder concerns, trying to find a satisfactory solution to problems and issues (often around confidentiality). Advisory Committee members interviewed were appreciative of the clear and useful information presented at the meetings.

How the PMP is doing so far:

Stakeholders reported that the PMP had been successfully implemented and was working well so far. Early use of Threshold Reports and Patient History Reports appear to have gone well. Both state medical associations reported that their members participating in the PMP seem pleased by the program and that there was anticipated excitement over the program having an on-line portal (scheduled for implementation in early 2006.) Early concerns over patient confidentiality or the potential use of PMP data by law enforcement, and a potential “chilling effect” have not materialized. Reporting of data from dispensers to the data contractor has improved steadily over time, both with respect to the timeliness and the accuracy of the data. Similarly, the generation of threshold reports has improved with respect to how low or high to set the threshold and for regularity and timeliness of the reports.

Concerns and issues:

There were relatively few and minor concerns and issues raised about the program to date. (Issues that were raised included calibrating the level on threshold reports a bit better; more timely access to the database; more timely and consistent submission of data to the data contractor, particularly by smaller and non-computerized pharmacies). Rather, the issues that were raised concern the challenge the PMP faces in continuing its excellent start and in growing the program. One stakeholder cautioned that while the PMP has done an excellent job in maintaining confidentiality even one well-publicized breach of confidentiality could hurt the program politically. Several stakeholders noted the need to secure and maintain external funding and that any effort to shift some of the costs of the program onto participants could jeopardize the program.

It was noted that the program will need to continue to grow and have more registered prescribers actively using the database. There is a “tipping point” issue here that involves both improving the speed of access to information (where clinicians can get information back when the patient is with them) and more clinicians knowing about and using the database. Doctors are very busy and have many competing administrative and clinical demands on their time.

The trade-off between accuracy and confidentiality of information and the speed and usefulness of this information remains. There is considerable excitement and enthusiasm about the PMP WEB Portal which will offer enhanced access to prescribers and dispensers. Yet creating this access (almost universally desired by prescribers and dispensers) increases the potential for security violations (however small this chance may be). Under the present system there is an opportunity for someone to review manually requests for reports. This will not be true under the new web portal. However, there is very little information in these requests that is likely to raise an issue. As a result, consensus exists that the benefits of quick access for providers, particularly emergency room doctors, far outweighs the slightly reduced oversight.

Recommendations for measuring the outcomes of the PMP:

Stakeholders recommended that process, or intermediate, indicators of outcome should include the number of patients identified and treated for substance abuse and the number of actively participating providers and requested patient history reports, and the number of prescription drug arrests (for which one would expect to see a decrease if the

PMP was identifying patients earlier and getting them to treatment). Stakeholders noted that true outcome measures might include reduction in the amount of diverted drugs on the street, reduction in deaths involving a prescription drug overdose, reduction in the number of youth reporting illicit prescription drug use. However stakeholders recognized that it would be difficult for the PMP to achieve these impacts in the short-term and that measuring such impacts might be difficult.

Recommendations to OSA:

Stakeholders want OSA to increase prescriber and dispenser access to the database, but otherwise want OSA to continue the excellent job it is doing and to “stay the course.” This question elicited effusive praise among a number of respondents. The Director of OSA was praised for her inclusiveness and responsiveness in listening to and responding to stakeholder suggestions. OSA has maintained a steady focus on the prevention and treatment goals of the program.

OSA and Chris Baumgartner were praised for running a very lean and highly efficient data monitoring program that is timely, responsive, and provides very clear and useful information. Mr. Baumgartner is very highly regarded. It was recommended that OSA keep the program streamlined and clear. It was recognized that it would be helpful to OSA to have more funds with which to do this.

IV. Prescriber and Dispenser Surveys

Prescriber Survey

Overview: A survey was mailed to the 350 prescribers who had registered as a prescriber under the PMP Program. We limited our sample to this group because these prescribers were likely to have some familiarity with the PMP program (by virtue of having registered). One-hundred and thirty-six prescribers completed the survey, for a response rate of 38.9 percent. Nearly one of five prescribers indicated that either they didn’t register (11.0 percent) or didn’t know whether they had registered (7.4 percent). The majority of prescribers (81.6 percent) knew that they had registered and reported that the process for registering was clear and understandable (70.3 percent).

The vast majority of respondents were either familiar (70.6 percent) or very familiar (19.1 percent) with the PMP program (Table 1). Prescribers learned about the PMP program through a variety of ways (in order of most to least common): mailing, information pamphlet, professional association; PMP website; colleague/employer (Table 2).

Table 1. Familiarity of Prescribers with
Maine Prescription Monitoring Program

How familiar are you with the PMP Program?	Percent	(n)
Very Familiar	19.1	(26)
Familiar	70.6	(96)
Unfamiliar	8.1	(11)
Not at all familiar	2.2	(3)
Total	100.0	(136)

Table 2. How Prescribers Learned About
Maine's Prescription Monitoring Program
(Sources of information are not mutually exclusive)

How did you learn about your responsibilities and rights under the PMP? (check as many as apply)	(n)
Professional Association	29
Information Pamphlet	33
PMP Website	18
Mailing	54
Training Session	6
Colleague/ employer	9
Other	8
Not familiar with program / NA	13

Threshold Reports: Nearly three out of four prescribers (71.3 percent) reported receiving a threshold report on one or more of their patients. The vast majority of these respondents found the threshold report easy to understand (94.5 percent) and helpful (80.4 percent). Two-thirds of the respondents indicating that they had received a threshold report gave an answer to the question "What happened as a result of the report?" Their responses (which allow for multiple answers) indicate that the threshold

report was being used much as the PMP program hoped it would be – to serve as a potential flag for possible abuse and to result in follow-up action.

- Placed Information in patient's record; spoke with patient (n=10)
- Communicated with other providers, pharmacies (n=10)
- Confirmed that patient was not misusing prescriptions/abusing substances (n=9)
- Confirmed that patient was doctor shopping, abusing substances (n=8)
- Reduced / eliminated prescriptions for patients (n=12)
- Dismissed patient from practice (n=5)
- Referred / recommended substance abuse treatment for patient (n=4)
- Nothing (n=12)
- Other (n=3)

Patient History Report: Just under half of the respondents had requested a patient history report; three out of four of those requesting the patient history file found it useful (Table 3). Over half (61 percent) of those who had not requested a patient history report expected to request one over the next six months.

Table 3. Prescribers' Requesting a Patient History Report

Have you requested a Patient History Report about the prescriptions filled by one or more of your patients?	Percent	(n)
Yes	45.6	(62)
No	50.7	(69)
DK/NA	3.7	(5)
Total	100	(136)
Was the report helpful?		
Yes	75.8	(47)
No	9.7	(6)
DK/NA	14.5	(9)
Total	100	(62)
If you have NOT requested a Patient History Report, do you expect that you will request one over the next six months?		
Yes	60.9	(42)
No	24.6	(17)
DK/NA	14.5	(10)
Total	100	(69)

Slightly under two-thirds of the respondents (63 percent) indicating that they had requested a patient history report gave an answer to the question “What happened as a result of the report?” Their responses (which allow for multiple answers) indicate that the patient history report was being used much as the PMP program hoped it would be – to serve as a potential flag for possible abuse and to result in follow-up action. (The one finding of some concern is that 5 respondents reported that they had requested a report and never received one.)

- Placed Information in patient’s record; spoke with patient (n=3)
- Communicated with other providers, pharmacies (n=6)
- Confirmed that patient was not misusing prescriptions /abusing substances (n=8)
- Confirmed that patient was doctor shopping, abusing substances (n= 6)
- Reduced / eliminated prescriptions for patients (n=7)
- Dismissed patient from practice (n=2)
- Referred / recommended substance abuse treatment for patient (n=2)
- Nothing (n=4)
- Other (n=4)

Concerns About PMP Program: Twenty-one percent of the respondents had a concern about the PMP program. The major concern, by far, was that there was too long of a delay between requesting and receiving information (n=14). Prescribers wanted real-time, internet-based access that would help them when their patients were in their office or emergency room.

- Too long of a lag between requesting and receiving information; need real-time, internet-based access (n=14)
- Concerns about registering for and using the program (e.g. registration, accessing it, forgot password) (n=8)
- Data, reporting accuracy; matching patients to database. (n= 6)
- Don’t know enough about the program; need to find out more (n=4)
- Other (n=4)

The most common recommendation for improving the PMP is to reduce the time lag between requesting and receiving data (n=24); other common recommendations were to Improve the process for registering and using the program (n=14) and to provide better information about the program (n=9).

Dispenser Survey

Overview: A survey was mailed to 66 registered dispensers; 21 returned completed surveys (31.8 percent response rate). Nearly all respondents were very familiar (n=9) or familiar (n=11) with the PMP program (Table 4). Most respondents thought that the data contractor and OSA staff were very helpful (n=12) or somewhat helpful (n=4) in answering questions about the requirements and procedures of the PMP program (Table 5). The most common questions dispensers had about the PMP program were about software and implementation issues (n=6) and general data reporting requirements (n=6). The majority of dispensers thought the reporting requirements under the PMP program were easy (n=13) or very easy (n=10). Only a fourth of respondents thought that the reporting requirements were somewhat difficult (n=3) or very difficult (n=2).

Usefulness of PMP Program: Respondents were evenly divided about whether or not the PMP program was useful (somewhat or very) or not useful (not very / not at all) to their pharmacy. Less than half (n=8) of the dispensers had requested a patient history report and only six of those eight found the report helpful. Only a third of those not requesting a patient history reported that they expected to request a report over the next six months. Dispensers requesting a patient history report were asked what happened as a result of that report. The most common result was that it was confirmed that the patient was "doctor shopping."

Table 4. Familiarity of Dispensers With
Maine Prescription Monitoring Program

How familiar are you with the purpose and requirements of the PMP program?	Percent (n)
Very familiar	42.9 (9)
Familiar	52.4 (11)
Not familiar	4.7 (1)
Not at all familiar	0.0 (0)
Total	100.0 (21)

Table 2. Helpfulness of PMP Data Contractor and OSA Staff

How helpful were the Data Contractor and the OSA staff in answering questions about the requirements and procedures of the PMP?	Percent (n)
Very helpful	57.1 (12)
Somewhat helpful	19.0 (4)
Not very helpful	4.8 (1)
Not at all helpful	4.8 (1)
NA	14.3 (3)
Total	100.0 (21)

Concerns about the PMP Program: Half the respondents (n=11) reported concerns about the PMP. The most common concern was that it was too long of a lag between requesting and receiving information (n=4); a related concern was that there should be proactive reporting to pharmacies (n=2). Not surprisingly the most common recommendation for improving the PMP program was to reduce the time lag between requesting and receiving information.

V. Discussion and Recommendations

The PMP has been implemented successfully and is meeting its current goals. By all accounts, the Office of Substance Abuse has done an excellent job in developing and implementing the program. Stakeholders lauded the Office of Substance Abuse for (1) establishing and maintaining a prevention and treatment goal for the PMP (and not a law enforcement goal); (2) listening to the medical and other stakeholders in establishing and implementing the program, and (3) its extensive outreach and educational efforts. Chris Baumgartner, the PMP data manager and currently the acting PMP Director was praised for his technical expertise, clarity, and availability to answer any questions or concerns.

Prescriber registration for the program is increasing and, in general, prescribers have requested and used Patient History Reports as intended.

To meet its longer term goals, the PMP must continue to increase the number of registered prescribers actively using the program and its database. This requires that the number of prescribers registered and actively using the program continue to increase. There is every reason to believe this will happen. Prescribers currently using the program find it very useful and an important source of information (and encouragement) for other prescribers registering and using the program. Nevertheless prescribers are very busy and face increasing administrative and clinical demands from many sources in their day-to-day clinical practice.

Generally, dispensers have participated in and realized the benefits of the PMP as it was designed. Compared to the prescribers, there may be a bit more “wait and see” attitude among dispensers as to the utility of the Program, relative to their reporting requirements. Continued technical refinements in the database system (primarily involving reducing the time between requesting and receiving information) should continue to bolster the support and use of the program by dispensers.

It is important that the PMP maintain its exemplary record of data security and confidentiality. One of the sticking points in establishing the needed support for the PMP was the assurance of data security and confidentiality. The PMP has an unblemished record in maintaining this security but even a single incident, if well publicized, could affect future support for the program. This creates an on-going challenge for the PMP to balance the needs of data users to have “real-time” access to the data with the need to maintain data security and confidentiality.

The PMP has established credibility and core support within Maine’s medical community for this program. For the most part, prescribers who are engaged in this program are using it and realizing the benefits intended by the developers of the program. The PMP should continue to expand this support and extend the number of actively participating prescribers by:

- Providing ongoing outreach and information sessions
- Providing accessible technical assistance to remind prescribers how to register and use the system (including finding the password they may have forgotten)
- Reducing the time for prescribers between requesting and receiving information.

There needs to be reduced turn-around time, which the PMP has been working on. In some ways, the PMP may be a victim of its own success, in that it has been moving toward and promoting web-based access since the inception of the program and some prescribers are impatient as to when this will occur and what this will be. The PMP Advisory Group and participating Medical Associations will need to continue to play the important role they have in helping the PMP to engage active prescriber users of this system.

Given its successful implementation, the PMP Program should begin to consider longer-term issues of sustainability and how the program may be used to booster the public health substance abuse prevention goals of the state. Under a separate, but potentially related initiative - Strategic Prevention Framework, State Incentive Grant (SPF-SIG) - Maine is currently undertaking a major transformation of its public health and substance abuse prevention infrastructure and has identified reducing abuse of prescription medication as a major objective for local communities to address. Areas of strategic convergence between the PMP and SPF-SIG programs should be identified and explored.

The authoring legislation creating Maine's Prescription Monitoring Program required that external funding be secured for the program to be implemented. Maine has been successful in maintaining this funding, but its dependence on external funding creates a potential vulnerability to sustaining this excellent program over time.

ENDNOTES

ⁱ A Bill to create the Maine Prescription Monitoring Program had been introduced, but not passed, in the two previous sessions of the Maine Legislature. The major issue thwarting passage in these earlier sessions was concern over the stringency of data security and confidentiality.

ⁱⁱ Under current Maine law, medical doctors (MDs and DOs), dentists, nurse practitioners, and physician assistants all have prescribing privileges. The vast majority of clinicians prescribing Schedule II, III, or IV drugs are medical doctors.